

REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

Claims 1-15 are pending. Claims 11-15 stand withdrawn. Claims 1-6 are amended herein. New claims 16-20 are added. Basis for the amendments and new claims may be found throughout the specification and claims as-filed, especially at page 2, lines 11-13, page 3, third paragraph, and on page 4, second paragraph, page 5, fourth paragraph and page 6, first paragraph and page 19 (Example 4), page 21 (Example 5) and Figure 6. Thus, no new matter is submitted by way of the present Amendment. Applicants reserve the right to file at least one continuation or divisional application directed to any subject matter canceled herein.

Sequence Listing

Further to the Office Action on page 5, the Examiner indicates that a substitute sequence listing and CRF are not necessary if all of the sequences are accounted for and only amendments acknowledging sequence identifiers are required. As this is the case, Applicants have not provided a new CRF or paper copy of the sequence listing of October 23, 2002 herewith. However, amendments to the specification and claims, as well as to Figure 6, reciting the appropriate sequence identifiers are made herein.

Claim Rejections Under 35 U.S.C. § 101

Claims 1-6 stand rejected under 35 U.S.C. § 101, as the claimed invention is purportedly directed to non-statutory subject matter. The Office Action states that the claims encompass a naturally occurring nucleic acid molecule. As suggested by the Examiner, claim 1 is amended to recite an isolated nucleic acid molecule. In light of this amendment, Applicants submit this rejection is obviated.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the written description requirement.

Specifically, the claims stand rejected because the specification purportedly lacks support for claim 1, as drawn to a nucleic acid molecule comprising a nucleic acid sequence encoding a protein having the biological activity of MCP-I, which purportedly differ from the nucleic acid sequences described in the specification. Thus, the Office Action states the claims encompass a genus of nucleic acid sequences that is indeterminant in size, but could possibly encompass thousands of different nucleic acid sequences.

In order to clarify the claimed subject matter, and without acquiescing in the rejection, the claims are amended herein to reference the specific and published sequences in the claims. The claims are further amended to clearly define the sequence variants by reference to hybridization as well as the degree of homology. In this regard, Applicants refer to pages 3-4 of the specification, which provides a detailed discussion of hybridization and sequence identity and homology of the claimed nucleic acids. Thus, the claims as amended herein recite sequence homologs and do not recite functional homologues of MCP-1.

As the claimed subject matter herein is legally supported in the specification, Applicants request that the rejection be withdrawn.

Claims 1, 5 and 6 stand rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the written description requirement. Specifically, the Office Action states that the specification lacks support for claim 1, element b, which recites hypersensitive sequences containing mutations resulting in a modified DNase 1 hypersensitivity, Si hypersensitivity, and/or altered interaction with a transcription factors.

Without acquiescing in the rejection, independent claim 1 and claim 5 are amended herein to remove reference to modified hypersensitivity and instead to characterize the mutations by the degree of identity of the mutated sequence.

New claim 17 is added herein, reciting specifically disclosed regulatory sequences. New claims 18-20 are added (and claim 6 is amended herein to depend

on claim 20), reciting that the hypersensitive regions comprise binding sites for transcriptional factors.

In light of the above remarks and amendments, Applicants request that this rejection be withdrawn.

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, as purportedly lacking enablement for recited subject matter such as a nucleic acid comprising a nucleic acid sequence encoding a protein having the biological activity of MCP-1, and 5'-DHSRs or 3'DHSRs that do not explicitly comprise TGAGTCA or SEQ ID NO. 1 or SEQ ID NO. 8. Applicants traverse.

The Office Action states that the hypersensitive sites according to claim 1, element b, are not sufficiently enabled. In response, Applicants note that the specification discloses that the claimed nucleotide stretches of claim 1(b) refer to the published sequence data of Ueda et al. (1994). Thus, the skilled artisan would readily have access to this sequence data and thus the specific sites. See page 19 (Example 4) and page 21 (Example 5).

Further, claim 1 is amended herein to recite the published nucleic acid sequence of the MCP-1 gene and homologs thereof. Thus, Applicant submit that the claimed subject matter as amended is enabled, and that the skilled artisan would be easily able to identify the claimed nucleotide sequences referred to in element b of claim 1. In fact, these sequences are involved in the regulation of the expression of MCP-1, because of the published sequence data of Ueda *et al.* (1994) and Rollins *et al.* (1989), respectively. Applicants note that claim language in claim 1, element b recites "transcriptional start site of the MCP-1 gene", referring specifically to the nucleotide sequences of element a, and do not refer to "any" sequence.

New independent claim 16 is added herein. New claim 16 is directed to an isolated nucleic acid molecule wherein the regulatory nucleotide regions are defined by their specific sequence identifiers.

In light of the above comments, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claim Rejections Under 35 U.S.C. § 102

Claims 1-4 and 6-10 stand rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Genbank Accession No. AC005549 (via Birren et al.).

Birren et al. (via Genbank Accession No. AC005549) purportedly disclose a bacterial artificial chromosome (BAC) comprising a portion of chromosome 17 that comprises SEQ ID NO. 1, as well as the genomic DNA encoding the MCP-1 gene. The Office Action states that Birren et al. indicates that this sequence matching SEQ ID NO. 1 is comprised of BAC, wherein the BAC also includes a genomic sequence encoding MCP-1, and that Birren discloses all of the limitations of the instant claims. Applicants respectfully traverse.

"[A]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention as arranged in the claims." *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 U.S.P.Q. 253, 256 (Fed. Cir. 1985). The cited reference fails to describe or even suggest all of the elements of the rejected claims.

Birren *et al.* solely disclose the sequence of chromosome 17. Birren *et al.* fail to describe any functional features of the sequence. In particular, Birren *et al.* do not disclose any stretches or regions within the sequence that are involved in the transcriptional regulation of the expression of MCP-1, such as the claimed hypersensitive regions.

Further, the regulatory regions recited in the present claims are not derivable from the sequence data of Birren *et al.* because Birren *et al.* do not teach that the claimed nucleotide stretches are hypersensitive regions. Thus, the skilled artisan would not be enabled by the teaching of Birren *et al.* to practice the invention, especially with regard to these regions. The skilled artisan would not be able to identify the cis-acting sequences on which the regulation of MCP-1 gene expression is dependent, from the plain disclosure of the chromosome 17 sequence data in Birren *et al.* Therefore, Birren *et al.* do not recite all limitations of claim 1.

In light of these remarks, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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By: _____



Deborah H. Yellin
Registration No. 45,904

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620